UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,533	08/11/2006	Herwig Brunner	P/2107-281	1624

2352 7590 03/30/2009

OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK, NY 100368403

EXAMINER	
HADDAD, MAHER M	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
03/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/547,533	BRUNNER ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,6,17,25,35,36,47,50,55,75,82,89,95,105,108,122-123,128 and 132-138.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,6,17,25,35,36,47,50,55,75,82,89,95,105,108,114,115,122,123,128 and 132-138.

DETAILED ACTION

1. Applicant's amendment, filed 8/31/05, is acknowledged.

2. Claims 1, 6, 17, 25, 35-36, 47, 50, 55, 75, 82, 89, 95, 105, 108, 114-115, 122-123, 128, 132-138 are pending.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 6, 17, 25, 35-36, 47, 50, drawn to a method for at least one of identifying and detecting T-cell epitopes of a protein antigen in vitro, where a population of peptide fragments of the antigen is subjected to competitive binding to a first immobilized receptor unit, preferably in the presence of a second receptor unit which, together with the first receptor unit, is capable of forming a receptor, where at least one peptide fragment with affinity to the receptor binds to at least the first, receptor unit(s), and the bound peptide fragment is then isolated and analyzed.

II. Claims 55 and 75 and 138, drawn to a method for at least one of identifying and preparing a peptide vaccine against a protein antigen, where an amino acid sequence of a T-cell epitope of the protein antigen is identified in vitro, a peptide having the identified amino acid sequence is prepared and a peptide-presenting major histocompatibility complex (MHC) is prepared using the prepared peptide and a first and second chain.

III. Claim 82, drawn to a method for controlling the quality of receptor/ligand complexes and/or components thereof, which comprises preparing or providing a receptor/ligand complex in solution of two receptor units, where at least one receptor unit has a first functional group, and a ligand, immobilizing the receptor/ligand complexes on nanoparticles which have, on their surface, at least one second functional group which binds the first functional group, and analyzing the nanoparticles having the immobilized receptor/ligand complex using a MALDI method.

IV. Claims 89, 95 and 105, drawn to a method for preparing nanoparticles having, on their surface, at least one immobilized receptor unit or one immobilized receptor.

V. Claims 108 and 135, drawn to a method for at least one of enriching and isolating specific CD4+-T-lymphocytes or CD8+-T-lymphocytes from peripheral blood mononuclear cells (PBMCs).

VI. Claims 114 and 136, drawn to a method for at least one of priming and re-stimulating a CD4+-T- or CD8+-T-lymphocyte reaction in vitro.

VII. Claims 115 and 122-123, drawn to a nanoparticle, comprising on the surface at least one receptor unit.

VIII. Claims 128 and 134, drawn to a peptide vaccine which comprises at least one peptide-presenting MHC molecule and/or which comprises at least one protein antigen which contains a T-cell epitope.

IX. Claim 132, drawn to a kit for at least one of identifying and detecting T-cell epitopes of a protein antigen in vitro, comprising a container with a suspension of nanoparticles having an immobilized MHC molecule as claimed in claim 122 or a container with a suspension of nanoparticles having an immobilized first chain of an MHC molecule as claimed in any of claim l15 and a container with a lyophilizate of a second chain.

X. Claim 137, drawn to a method for the active immunization of an animal or human organism against a protein antigen wherein a peptide vaccine as claimed in claim 128 is used.

Note Absent evidence to the contrary, each of the recited receptor units, receptor/ligand complex, receptor/peptide fragment, immobilized MHC molecule, a peptide-presenting MHC molecule, peptide vaccine is distinct since each receptor units, receptor/ligand complex, receptor/peptide fragment, immobilized MHC molecule, a peptide-presenting MHC molecule, peptide vaccine is specific for is not obvious over the other set of receptor units, receptor/ligand complex, receptor/peptide fragment, immobilized MHC molecule, a peptide-presenting MHC molecule, peptide vaccine. Therefore the instant claims 1, 6, 17, 25, 35-36, 47, 50, 55, 75, 82, 89, 95, 105, 108, 114-115, 112-123, 128, 132-138 encompass hundreds of GROUPS, not species.

4. Accordingly, Applicant is required to elect a specific receptor such as MHC class I or class II, a specific first and second receptor unit; a specific receptor/ligand complex; a specific receptor/peptide fragment; a specific peptide vaccine; a specific immobilized MHC molecule; a specific peptide-presenting MHC molecule; or a specific receptor/peptide fragment, as appropriate for the ELECTED GROUP.

5. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group VII was found to have no special technical feature that defined the contribution over the prior art of US Pat. No. 5,885,527 (see entire document).

The `527 patent teaches that nanoparticles can be coated with receptor and the resulting nanoparticles can be immobilized to the diagnostic element through adsorbtion or covalent bonds (see col., 12, lines 64-66 and col., 13, lines 24-25 in particular).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

6. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;
(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
(d) the prior art applicable to one invention would not likely be applicable to another invention;
(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Species Election

7. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group V or VI is elected, applicant is required to elect either a CD4+ T-lymphocytes or CD8+ T-Tlymphocytes. CD8+ or CD4+ cells are distinct because they produce different cytokines with immunosuppressive effects; thus each cell type represents patentably distinct subject matter.

B. If Group VII is elected, applicant is required to elect whether the ananoparicale having (a) an immobilized MHC molecule or (b) a peptide-presenting MHC molecule. These are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species,** including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 25, 2009

/Maher M. Haddad/
Maher M. Haddad, Ph.D.
Primary Examiner
Technology Center 1600